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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,891	10/15/2003	Amir J. Tehrani	4014.10-1	7544

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EXAMINER

ALTER, ALYSSA M

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Tate

Office Action Summary	Application No. 10/686,891	Applicant(s) TEHRANI, AMIR J.	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,6,53-58,71-74 and 94-122 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,6,53-58,71-74 and 94-122 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>07/27/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on June 10, 2005 (paper No. 2) has been received and considered. By this amendment, claims 1-4, 7-52, 59-70 and 75-93 have been cancelled, claims 5-6, 53-58, 71-74 and 94-99 have been amended, claims 100-122 have been added and claims 5-6, 53-58, 71-74 and 94-122 are now pending in the application.

Response to Arguments

Applicant's arguments with respect to claims 1-99 have been considered but are moot in view of the new ground(s) of rejection with Testerman et al. (US 5,522,862).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 5-6, 53-58, 71-74 and 94-122 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51-53 of copending Application No. 10/966484 (US Patent Publication

20050085869 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both stimulate the diaphragm with electrodes for the treatment of respiratory disorders or disease with stimulation pulses that varying in amplitude and/or frequency.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 5-6, 53-58, 71-74 and 94-122 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/966472 (US Patent Publication 20050085867 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both stimulate the body with an electrode for the treatment of respiratory disorders or disease by controlling breathing in conjunction with breathing or respiratory parameters, including respiratory tidal volume, exhalation, minute ventilation, partial pressure of carbon dioxide in a patient's blood and the level of oxygen in a patient's blood.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 5-6, 53-58, 71-74 and 94-122 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 and 26-38 of copending Application No. 10/966421 (US Patent Publication 20050085866 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both stimulate the body in response to

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a sensed precursor for the treatment of respiratory disorders or disease by controlling breathing.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 5-6, 53-58, 71-74 and 94-122 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-33 of copending Application No. 10/966487 (US Patent Publication 20050085734 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both stimulate the body for the treatment of respiratory disorders or disease by controlling breathing.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 5-6, 53-58, 71-74 and 94-122 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-11, 15-27, 30-33 and 35-42 of copending Application No. 10/966474 (US Patent Publication 20050085868 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both stimulate the diaphragm with electrodes to elicit a respiratory response. The stimulation also treats respiratory disorder by affecting and/or controlling several respiratory parameters, such as exhalation, blood oxygen levels, expiration, minute ventilation, partial pressure of CO₂ and tidal volume.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 5-6, 53-55, 57-58, 71-74, 94-96 and 98-122 are rejected under 35 U.S.C. 102(b) as being anticipated by Testerman et al. (US 5,522,862). Testerman et al. discloses a typical respiratory effort waveform for two complete respiratory cycles in figure 2a. "Each wave of the waveform is characterized by a negative peak 30 on completion of expiration, a positive peak 35 on completion of inspiration and a turning point 40 which indicates the onset of inspiration. Each wave of the waveform can therefore be separated into a period of respiratory pause 32, an inspiratory phase 33 and an expiratory phase 34" (col. 5, lines 25-31). Therefore, sensing the respiratory waveform implicitly corresponds to the patient's inspiration rate and the exhalation rate.

Testerman et al. further discloses "a method for treating sleep apnea by bursts of electrical stimulation in response to sensed inspiration which includes detecting an arousal event and thereafter maintaining stimulation intensity in response to sensed inspiration below that which is perceptible to the patient. This level of stimulation is maintained for a predetermined period of time after detection of the arousal event in

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order to allow the patient to return to sleep without perceptible upper airway stimulation"(col. 2, lines 48-57).

As to claims 5-6, 57-58, 71-74, 98-105, 115 and 120, "a block diagram of the principal elements of a device which can accomplish this is shown in FIG. 5. That device includes a transmitter/controller 55, which is capable of sensing the inspiratory phase and transmitting an electrical stimulus pulse to muscles of the upper airway. The transmitter/controller 55 could be either an implantable or an external device but the following description will relate primarily to a battery powered external device. A respiratory transducer 60 such as a conventional belt transducer sends respiratory waveform information to the transmitter/controller 55 which sends stimulus pulses through an antenna/electrode system 65 to stimulate the muscles of the patient"(col. 6, lines 3-15). By sensing the stimulation waveform and then stimulating the respiratory muscles accordingly, Testerman et al. modifies the respiratory waveform and thus the inspiration rate and the exhalation rate.

As to claims 53-55 and 94-96, "the microprocessor 75 identifies the inspiration phase of the waveform so that the system can supply a shaped stimulus burst for the duration of that phase at the antenna output 100. The microprocessor 75 is coupled to a dual digital/analog converter 105, which is also coupled at its output to analog circuitry, which acts as a stimulus shaper 110. These elements work in combination to provide a shaped "stimulus window" which controls when stimulation will be provided and how much stimulation will be provided at the antenna output 100. The RF coupled stimulus burst is provided within this window. The microprocessor 75 sets the digital values for

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the digital/analog converter 105. The dual digital/analog converter 105 is connected in a cascaded arrangement with a first digital/analog section setting the amplitude of the stimulus pulse (i.e. from 0 to 8 volts in 256 increments of 32 millivolts) and the second digital/analog section setting the shape of the stimulus burst (i.e. the shape and duration of the stimulus during a rise time interval and a fall time interval as functions having 0-100% of full amplitude with eight bit resolution ($1/256$) for each 31 millisecond interval of output—typically, a linear ramping function of 250 millisecond for rise time and a linear ramping function of 125 millisecond for fall time is the default setting, or, to turn the stimulus on more quickly, a nonlinear ramping function, such as a sine function, could be used)"(col. 6, lines 13-28).

As to claims 108-111 and 116, "T1-T4 are monitored by the microprocessor 75. T1 is a measure of inspiratory rise time and is a sub-component of the active phase of inspiration. It represents the inspiratory rise time to a nominal 75% of peak value. T2 is the active inspiratory phase time. T3 is the active inspiratory/expiratory phase time. T4 is the length of a single respiratory cycle. In order to monitor these values, the microprocessor 75 needs to find the inspiratory turn point 242, the inspiratory peak PK1, the negative expiratory peak PK2, and the next inspiratory turn point 242a. In general, these points are found by various slope and/or amplitude criterion. Also monitored by the microprocessor are the PK1 and PK2 amplitude values for each phase. Average values of these variables may be computed and stored in the memory of the apnea treatment device in order to allow any method used to analyze the respiratory waveform or any method used to detect the onset of an apnea to adapt to normal variations in the

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waveform that may occur during sleep”(col. 9-10, lines 57-67 and 1-7). The examiner further considers the inspiration time to be the same as the inspiration duration.

As to claim 109 and 117, “FIG. 4a shows that in a normal respiratory effort waveform 43, the inspiratory peaks 45 a-d are of approximately the same amplitude. By comparison in FIG. 4b, in a waveform 47 the inspiratory peaks 50 a-d become significantly greater in amplitude at the onset of obstructive apnea than the immediately preceding inspiratory peak 52. This is reflective of the increased inspiratory effort undertaken by the patient in response to the difficulty of breathing through the obstructed airway”(col. 5, lines 48-56). Since Testerman et al. treats apnea, the increase inspiratory effort or increase in inspiratory peak amplitude as a result of apnea is reduced. Thus, Testerman et al. modifies the inspiration amplitude.

As to claims 113-114, “during a first period indicated as 53a, stimulation is enabled producing a normal respiratory airflow”(col. 5, lines 64-66). Therefore, Testerman et al. treats apnea by returning the patient’s respiration to normal respiratory and thus, to a predetermined respiratory waveform.

As to claims 106-107, 118-119 and 121-122, modification of the inhalation and exhalation rate will inherently affect the levels of oxygen and carbon dioxide in the patient’s blood, since respiration directly affects blood gas equilibrium.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 56 and 97 are rejected under 35 U.S.C. 102(b) as anticipated by Testerman et al. (US 5,522,862) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Testerman et al. (US 5,522,862) in view of Geddes et al. (US 4,827,935). Testerman et al. discloses the adjustment of several parameters, such as frequency, pulse duration, and therefore it is capable of being adjusted to control tidal volume.

In the alternative, Testerman et al. discloses the claimed invention except for the tidal volume. Geddes et al. teaches that it is known to modify tidal volume as set forth in column 7, lines 28-32, with increased stimulation to increase tidal volume. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the stimulation treatment as taught by Testerman et al. with the stimulation to modify the tidal volume as taught by Geddes et al., in order to increase the volume of air inspired to assist in the respiration of the patient.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

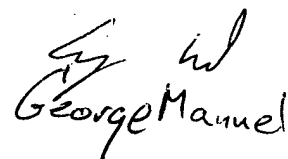
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Alyssa M Alter
Examiner
Art Unit 3762


George Manuel